REMARKS and ARGUMENTS

In the December 15, 2003 Office Action, claims 9, 10, 12, 13, 21, 23, 26, 27, 33 and 34 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite. In addition, claims 1-15, 17-21, 23, 24, 26-35 have been rejected under 35 U.S.C. 103(a). Claims 24 and 26-30 were rejected as being improper kit claims. In response, Applicant has canceled claims 24 and 26-30.

In reviewing the Action, Applicant respectfully believes that the finality of the rejections is improper and that the prior art applied to the claims clearly does not render the claims unpatentable. Therefore, Applicant respectfully requests withdrawal of the finality and allowance of the claims in view of the following comments.

General Arguments

Applicant contends that the previous two Office Actions were improper because neither complies with MPEP 706.02(j). Each action has failed to provide any of the evidence enumerated in paragraphs (A) through (D) of the above cited MPEP section. Nor have the actions met the three prima facia case of obviousness criteria. The Actions have presented only general assertions that the combined references may teach Applicant's invention.

Furthermore, the Final Office Action failed to address all of Applicant's arguments presented in response to the First Office Action. For example, Applicant argued with respect to claim 20:

Independent claim 20

> Applicant submits that this combination of references does not disclose, teach or suggest the method recited in independent claim 20. Specifically, this combination does not disclose, teach or suggest *using a laser* to separate the internal area of the cornea offset from the main optical axis into first and second *substantially ring-shaped* internal surfaces to form a corneal pocket and using a laser to ablate a portion of the cornea *overlying the portion* of the first surface that remains *attached* to the second surface by the area *located at the main optical axis*.
>
> By forming a substantially ring-shaped corneal pocket offset from the main optical axis, the curvature of the eye can be changed without the portion of the eye along the main optical axis being disturbed. This results in a less likelihood that the healing of the cornea will result in halos or other vision impairments.

(Pages 15-16 of Response to First Office Action dated August 30, 2003)

But no where in the Final Office Action are these specific arguments addressed. In response, the Action merely repeats the 35 U.S.C. 103(a) rejection from the previous Office Action without pointing out specific column and line numbers where a motivation or a suggestion to combine the references is identified.

Therefore, if this application is not allowed, Applicant respectfully requests a further non-final Office Action.

Response to 35 U.S.C. §112, Second Paragraph Rejection

The rejection of claims 9, 10, 12, 13, 21, 23, 26, 27, 33 and 34 have under 35 U.S.C. 112, second paragraph for indefiniteness is allegedly because they "merely recite the use of particular structure, thus what further manipulative aspect of the method is intended to be specified is unclear". (Page 2 of the Final Office Action). However, United States Court of Appeals for the

Federal Circuit opinions have construed structural recitations in a method claim step as a proper limitation on the claim. Moleculon Research Corp v. CBS, Inc., 229 USPQ 805, 812 (Fed. Cir. 1986). Additionally, one of ordinary skill would know that introducing a lens into an internal pocket located in the cornea would require a different manipulative aspect than introducing ocular gel into the same internal pocket. Such a limitation is within the boundaries of permissible patent practice as stated in MPEP 2173.01. MPEP 2173.01 states that applicants may use any style of expression or format of claim that makes clear the boundaries of the subject matter for which protection is sought, and cited In re Swinehart, 160 USPQ 226 (CCPA 1971), which holds that a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

Furthermore, the Action provides no rationale for the rejection of claim 26. However, the structure that is being added to the independent claim is a ring-shaped ocular material that requires a method of introducing different from non-ring-shaped ocular material when being adapted to be inserted. In regard to claim 27, the structure being limited by the claim is the setting of the laser energy to only ablate the surface of the cornea and not tissue within the eye that is to remain unablated.

The Action rejects dependent claims 9 and 10 because they further limit the type of ocular material introduced into the internal pocket and not the method required to insert the lens into the internal pocket. As to claim 10, a ring-shaped lens would require a different method of introducing than inserting a non-ring-shaped into the same internal pocket. By limiting the

ocular material to specific types of ocular material (i.e. lens and ring-shaped lens) claims 9 and 10 are inherently limiting the method.

The Action rejects dependent claims 12, 13, 33, and 34 because they further limit the type of laser used to create the internal pocket within the cornea and not the method required to aim or fire the laser. But, in claims 12 and 33, one of ordinary skill would know that each specific type of laser (ultra short pulse versus the quasi-continuous laser of Bille) requires its own method of operation and manipulation to create an internal pocket located in the cornea. As to claims 13 and 34, a femto-, pico- and attosecond lasers clearly require different methods of manipulation due to the differences in duration of the laser pulse. By limiting the laser of claims 1 and 31, respectively, to specific types of lasers (ultra short pulse as opposed to quasi-continuous and further defining the pulse durations of the ultra short pulse laser to femto-, pico- and attosecond) the dependent claims are inherently limiting the method of independent claims 1 and 31.

Finally, as support for the structural limitations as outlined by Moleculon Research Corp, the Applicant discusses the use of ultra short pulse lasers and excimer lasers in various portions of the specification. Excimer lasers are discussed in paragraphs [0005], [0064], [0065], [0067] and figure 24, element 46 of the specification. Femtosecond ultra short pulse lasers are discussed in paragraphs [0004]-[0006] and [0052] of the specification. Picosecond and attosecond ultra short pulse lasers are discussed in paragraph [0052] of the specification.

For the above reasons, the 35 U.S.C. 112, second paragraph rejection of claims 9, 10, 12, 13, 21, 23, 33 and 34 should be withdrawn.

Response to 35 U.S.C. §103(a) Rejections

With respect to claims 1-4, 7-13, 17-19 31 and 34 and 35, Bille et al. does teach using a laser to internally ablate pockets in the stroma as show in fig. 5. However, Bille only suggests using these pockets for radial keratotomy or making T-cuts to correct for myopia, hypomyopia or astigmatism (See col. 10, ll. 34-45). Bille does not suggest that the pockets are continuous around the main vision axis, nor does Bille suggest introducing ocular material into the pockets to correct for myopia, hypomyopia or astigmatism as set forth in independent claims 1 and 31.

The Action then attempts to combine the procedure of Simon with the laser of Bille replacing the corkscrew delaminator of Simon because it "could form the intrastromal pocket much more precisely than the mechanical device of Simon". However, Simon does not suggest that his device suffers from a lack of precision. Additionally, Bille does not suggest any process or mechanism that insures the Action's claim of greater precision. Furthermore, the process of Simon centers on the use of the corkscrew delaminator. Thus, combining Simon and Bille is improper.

Neefe teaches two methods of obtaining the desired corneal curvature. The first is to apply a heated mold to the eye. The heat softens the corneal tissues and allows for the mold to shape the corneal surface. The mold can be heated in hot water, in an oven, by microwave or other radiation sources. (col. 1, lines 35-45). The second uses chemical agents present on the corneal mold to soften the corneal tissues. The chemicals are time released and eventually decay having no further effect on the corneal surface. Once the chemicals decay the corneal surface

should maintain the shape of the corneal mold. (col. 1, lines 20-30, col. 2, lines 5-7). Neefe's preferred embodiment uses a combination of the two methods (col. 1, lines 64-65).

However, the ocular material of the instant invention as set forth in claim 31 is transformable by irradiation and the use of Neefe's heated mold and subsequent irradiation (col. 1, lines 41-42) would change the volume of the ocular material causing an unevenness or bulge or flatness that was not desired or intended.

Regarding claim 1, the addition of Neefe's mold to the combination of Bille and Smith also does not address the situation of excess gel or insufficient gel present in Smith. Smith requires that the gel be massaged within the internal pocket to the correct surface curvature, thereby, modifying the cornea to the desired curvature. No further action is required to shape the corneal surface. If the gel in Smith is massaged out before placing the mold in Neefe, then the mold is not necessary.

Regarding claims 2 and 31, Simon discloses irradiated gel at the corneal incision site to close the wound, which reduces wound healing time and eliminates the need for the patient to wear a post-operative patch (col. 6, lines 14-20). Simon does not teach or suggest irradiating the gel within the channel created by the delaminator as set forth in claims 2 and 31.

To support the rejection, the Action also combines the corneal mold of Neefe with the combination of Bille and Simon to allegedly teach the claimed limitation of "placing a contact lens having a predetermined curvature on the external surface to shape the ocular material" as set forth in claims 2 and 31. The action correctly states that Neefe adjusts both the corneal surface

and the underlying ocular material, however, it is the manner of how Neefe accomplishes the adjustment that is unsuitable to the present invention.

Regarding claims 2 and 13, Bille teaches away from using pulsed laser beams as set forth in claim 13 because pulsed laser beams require relatively long periods of quiescence. Due to these periods of quiescence, it is necessary that the pulse be relatively high powered (see col. 1, lines 58-65). Bille specifically teaches using only a quasi-continuous laser beam and not an ultra short pulsed laser (col. 2, lines 32-34).

Thus in summary, the combination of Bille, Simon and Neefe does not suggest using a laser as a substitute for the corkscrew delaminator or substantiate the Action's claim of greater precision when a laser is substituted for the delaminator. Bille does not teach an ultra short pulse laser. Simon does not teach or suggest irradiating the ocular material within the corneal pocket only the excess that is exposed at the incision site. Furthermore, the corneal mold of Neefe is not required in the combination of Bille and Simon. Finally, the combination does not address the introduction of excess gel or insufficient gel.

Therefore, Applicant believes these arguments overcome the rejection of record and claims 1-4, 7-13, 17-19, 31 and 34 and 35 are in condition for allowance.

With respect to independent claim 20 and dependant claims 21 and 23, these claims are rejected over the combination of Bille and Simon further in view of L'Esperance, Jr. L'Esperance, Jr. teaches a method of ablating the surface of the cornea and preparing a donated cornea for implantation, but does not teach or suggest creating a substantially ring-shaped pocket

within the cornea with a laser and introducing ocular material in the corneal pocket. Therefore, L'Esperance, Jr. does not cure the deficiencies of Bille and Simon as argued above. Accordingly, claims 20, 21, and 23 are considered to be in condition for allowance.

Claims 1, 4-6, 14, 15 and 31-35 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al.(U.S. Patent No. 4,907,586) in combination with Neefe (U.S. Patent No. 3,776,230), L'Esperance, Jr. (U.S. Patent No. 4,665,913), and Simon (U.S. Patent No. 5,090,955).

As stated above, Bille, Neefe and Simon do not teach individually nor do they suggest or provide motivation for combining the three references to teach the claimed invention. The addition of L'Esperance, Jr. does not cure the above stated deficiencies of Bille, Neefe, and Simon.

L'Esperance, Jr. teaches a method of ablating the surface of the cornea and preparing a donated cornea for implantation, but does not teach or suggest creating a corneal pocket within the cornea with a laser and introducing an ocular implant in the corneal pocket. Therefore, L'Esperance, Jr. does not cure the deficiencies of Bille and Simon as argued above.

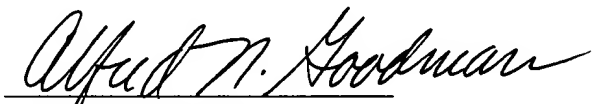
The final combination of Bille, Simon, L'Esperance, Jr., and Neefe does not suggest using a laser to create a corneal pocket as claimed or substantiate the examiner's claim of greater precision when a laser is substituted for the delaminator of Simon. Bille does not teach an ultra short pulse laser. Simon does not teach or suggest using the corkscrew delaminator to create corneal flaps. Furthermore, the corneal mold of Neefe is not required in the combination of Bille

and Simon. Finally, the combination does not address creating a corneal flap and introducing a corneal implant within the corneal flap.

Therefore, Applicant believes the above arguments overcome the rejection of record and claims 1, 4-6, 14, 15 and 31-35 are in condition for allowance.

In view of the above, it is believed that claims 1-15, 17-21, 23 and 31-35 of the present application are in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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